

TAB 57

LICENSE AGREEMENT

AGREEMENT effective as of January 1, 1995 between BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., a Delaware corporation, with its principal offices at 900 Ridgebury Road, Ridgefield, Connecticut 06877, U.S.A. (hereinafter called "BIPI"), and ROXANE LABORATORIES, INC., a Delaware corporation with its principal offices at 1809 Wilson Road, Columbus, Ohio 43228 (hereinafter called "ROXANE").

WITNESSETH:

WHEREAS, BIPI has pharmaceutical research and development facilities and is engaged in the development of new pharmaceutical specialties in finished dosage form, and has licensed-in and further developed a certain pharmaceutical specialty which is available for licensing;

WHEREAS, ROXANE is in the business of selling and promoting pharmaceutical specialties within the United States and is interested in licensing-in additional products;

WHEREAS, BIPI is willing and able to license and sub-license rights to certain pharmaceutical specialty products containing mexiletine to ROXANE under the terms and conditions set forth herein and ROXANE desires to receive such a license under such terms;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, the parties hereto do hereby contract and agree as follows:

1. DEFINITIONS

The terms defined in this section shall, for all purposes of this Agreement, have the meanings as defined in this section.

1.1 "Territory" means the United States of American abbreviated hereinafter as "USA", and shall mean all fifty states, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam and the territories and possessions of the USA.

1.2 "Know-how" means any and all trade secrets or other proprietary information and data relating to the Products as defined hereunder

developed by BIPI or acquired from others, including without limitation all manufacturing techniques, processes, formulae, specifications, and other manufacturing, formulating and analytical information; all safety, efficacy, pharmacological, toxicological, clinical and other laboratory and scientific data and information, for animal, human and any other use; and all marketing data, information and trade dress relating to the Products.

1.3 "Know-how Licenses" means a license for any and all Know-how which is now, or hereafter owned by BIPI or acquired from a third party by BIPI which BIPI is free to license and/or sublicense to ROXANE.

1.4 "Product(s)" means any and all molecules, chemicals, compounds, active ingredients and pharmaceutical specialty products in finished dose form containing mexiletine as an active ingredient which have been, or are in the future, invented, developed, and/or acquired by BIPI, whether or not patented or patentable, and as to which BIPI developed, or acquired under terms and conditions not prohibiting its disclosure and sublicense hereunder.

1.5 "Net Sales" means the gross amount invoiced on all sales of the Products by ROXANE, less:

1.5.1 value added, excise, and other taxes or duties either paid by ROXANE or included in the gross invoice price,

1.5.2 freight, postage, insurance and other transportation charges, and

1.5.3 cash and trade discounts, rebates, commissions, and credits due to outdating, rejection or return, provided they are actually granted and are in accordance with customary trade practice.

1.6 "Confidential Information" means all of the data and information which BIPI maintains as proprietary or trade secret information and data, whether developed internally or acquired from third parties with the right to disclose it to ROXANE including without limitation, the data and information defined as Know-how herein.

2. GRANT OF LICENSE

2.1 BIPI hereby grants to ROXANE for the term of this Agreement a non-transferable, non-exclusive license to use the Know-how in the Territory in connection with the manufacture and sale of Products in the Territory for the indications agreed upon by the parties hereto and otherwise pursuant to the terms and conditions set forth herein. This right includes the right to have the Products made for ROXANE by a third party approved by BIPI which approval shall not be unreasonably withheld (hereinafter "Licensed Third Party", within or outside the Territory using the Know-how.

3. EXCHANGE OF INFORMATION, DATA AND MATERIALS

3.1 Transmittal by BIPI - As such information, data, and documents become available from time to time, BIPI shall transmit or have transmitted to ROXANE copies of all of the Know-how in its possession. Such transmittal shall include without limitation all manufacturing and testing specifications for Products along with all commentaries and directions in BIPI's possession for the manufacture of finished dose forms of the Products and the active ingredients contained therein. In addition, BIPI undertakes to furnish to ROXANE at reasonable times and in reasonable amounts, specialized technical advice concerning the Products and to place at the disposal of ROXANE all of its experience in connection with the Products as BIPI deems to be necessary or appropriate. BIPI shall keep ROXANE fully informed as to all improvements of the Products and methods of manufacture thereof and all other improvements of the Know-how which BIPI shall make, own, or control during the term of this Agreement, and all such improvements shall be included in the licenses granted hereunder. Each party shall promptly furnish the other party with any and all information coming to its attention concerning any adverse effect, side effect, injury, toxicity, or sensitivity reaction, including unexpected incidents and the severity thereof, associated with any preclinical, clinical, or commercial use, investigation, or test of a Product in humans or animals whether or not determined to be attributable to a Product.

3.2 Transmittal by ROXANE - During the term of this Agreement ROXANE shall transmit to BIPI:

3.2.1 once per year, details of any significant improvements made in the Products, the results of any commercial and clinical experience with the Products, other significant information and data developed or acquired by ROXANE relating to the Products and Patents, and, if requested by BIPI, copies of any

submissions or communications to or from government health authorities concerning the Products;

3.2.2. prior to submission for publication, any and all scientific articles and papers concerning the Products prepared by, or on behalf of, ROXANE. Starting from the receipt of said documents, BIPI shall have one (1) month to inform ROXANE of its observations on the said articles and papers, it being understood and agreed that during this one (1) month period, the above mentioned documents shall not be submitted for publication; and

3.2.3 once per quarter, a report on the sales of each Product in the Territory by units and applicable monetary amounts.

4. CONFIDENTIALITY OF INFORMATION AND DATA

4.1 All Confidential Information delivered by BIPI to ROXANE hereunder shall be maintained by ROXANE in strict secrecy absent BIPI's approval of the proposed disclosures or any disclosures legally required to be made by law. ROXANE further agrees:

4.1.1 not to make any use whatsoever of any Confidential Information except for the purposes specified herein, either for itself or any other person, firm, or corporation;

4.1.2 not to reveal any Confidential Information to third parties except Affiliates of ROXANE and Licensed Third Parties and then only to the extent necessary to fulfill the purposes of this Agreement;

4.1.3 except as provided in Subsection 4.1.2 above, to keep all Confidential Information strictly secret and confidential and to that end, without limiting the generality of the foregoing, to cause all written materials relating to or containing any Confidential Information to be plainly marked to indicate the secret and confidential nature thereof, and to prevent unauthorized use or reproduction thereof;

4.1.4 to return all written material evidencing Confidential Information to BIPI upon termination of this Agreement; and

4.1.5 to impose the obligations of this Section 4 on those of its employees and Licensed Third Parties having access to all or any portion of the Confidential Information.

4.2 ROXANE's obligations hereunder shall not apply to:

4.2.1 any Confidential Information which, at the time of disclosure hereunder, is in the public domain;

4.2.2. any Confidential Information which, after disclosure hereunder, comes into the public domain through no breach by ROXANE, its Affiliates or Licensed Third Parties, of their obligations herein contained;

4.2.3 any Confidential Information which ROXANE can show was already in its possession at the time of disclosure hereunder;

4.2.4 any Confidential Information which is legally acquired by ROXANE from a third party who is not subject to a contractual or fiduciary relationship to BIPI with respect to said Confidential Information.

4.3 All Confidential Information delivered by ROXANE to BIPI shall be maintained by BIPI in strict secrecy in accordance with the secrecy commitment terms as hereinabove stated in Section 4.1.

4.4 Any Confidential Information which must be disclosed in order to obtain the governmental approvals anticipated by this Agreement or which is required to be disclosed by court order may be disclosed by ROXANE to such governmental agency or pursuant to such court order without breaching this Agreement.

5. PREPARATION OF DEVELOPMENT PROJECTS

5.1 Consistent with sound scientific and commercial principles and after having received from BIPI the information provided for in Section 3.1 hereinabove ROXANE shall draw up a development project for the Product(s) indicating in particular ROXANE's commercialization plans. Such development project shall be communicated in writing to BIPI and may be revised at any time and from time to time by ROXANE.

5.2 ROXANE shall send to BIPI an annual report on its commercial and development activity and an updating of the development project. In addition to the aforesaid annual reports, ROXANE shall promptly report to BIPI any unexpected or unusual findings which may develop as a result of its investigations of the Product(s) and any significant deviations from the development project.

5.3 The parties shall meet as often as is reasonably necessary in order to keep both parties fully informed as to the progress of research performed hereunder, if any; and, the commercial development of the Product(s).

6. GOVERNMENT APPLICATIONS

6.1 As soon as possible following the receipt of the Confidential Information from BIPI pursuant to Section 4.1 ROXANE shall initiate and diligently pursue marketing of Products with such activities as ROXANE, in its sole discretion, deems desirable consistent with the level of activity which ROXANE would expend upon its own products of like nature. ROXANE will assume all costs connected with its activity for the Products in the Territory.

6.2 If at any time during the term of this Agreement ROXANE decides not to continue marketing or distribution of a Product in the Territory after such marketing or distribution has commenced, ROXANE shall immediately inform BIPI in writing to this effect. Upon such notification, ROXANE agrees to make available to BIPI upon its written request, all data and information submitted by ROXANE to the government health authorities or other government agencies all data and information which is in its possession. The charge to BIPI for such data and information shall reflect the customary charges for the transfer of such information in the pharmaceutical industry but in no event shall it exceed ROXANE's actual out of pocket costs associated with the transfer. After such notification, ROXANE will, upon written request of BIPI, execute any documents necessary to transfer any government approval and other licenses to BIPI or to a third party designated by BIPI. Upon receipt of such notification, all licenses granted hereunder with respect to that Product shall terminate and BIPI shall be free to make, use, and sell the applicable Product or to grant a license to do so to a third party.


7. ROXANE TO FOSTER PRODUCTS

7.1 To the extent consistent with the interest of its business, ROXANE will use its best efforts to foster and develop the sale of Products in the Territory and to manufacture or have manufactured the Products in quantities required for sale in the Territory. In furtherance of this obligation, ROXANE agrees to transmit to BIPI at no charge, specimens of samples, displays, advertising copy, promotional literature and similar literature used by it from time to time in the marketing, advertising, and promoting of Products in the Territory promptly after preparation of same. In addition, ROXANE will use its best efforts to advise BIPI of the medical aspects of its advertising and promotion prior to the use thereof.

7.2 Marketing - Within one (1) year after receiving final governmental approval to market a Product in the Territory, ROXANE shall market the Product on a nationwide basis and deliver it for sale to the normal channels of the trade therein as if it were one of ROXANE's own products, unless such marketing or delivery is delayed because of BIPI's act or failure to act. Should ROXANE decide not to market a Product in a given country or territory within the time specified above, then the licenses granted hereunder shall terminate with respect to such Product in such country or territory, and BIPI shall be free to make, use, and sell the Product in that country or territory or to grant a license to do so to a third party.

8. BIPI AS POTENTIAL SUPPLIER

If ROXANE elects to exercise its right to produce active ingredients or manufacture Products, or exercises these rights only in part, BIPI agrees to supply to ROXANE or to use its best efforts to cause one or more third parties to supply to ROXANE, Products in finished dosage form, in semi-finished form, or the active ingredients contained therein, at the option of ROXANE. Supplies shall be at such prices as reflects the current market conditions for the supplies to be ordered, and upon such other terms and conditions as BIPI and ROXANE have mutually agreed upon from time to time.



9. IMPROVEMENTS

9.1 ROXANE shall grant to BIPI a non-exclusive royalty-free license, including the right to sublicense, to make, use and sell under any patents ROXANE may obtain covering the Products and any precursors, isomers, or derivatives thereof, and a non-exclusive license, with right to sublicense, to use all know-how ROXANE obtains or develops with respect thereto. For purposes of this Section 9, the term

"know-how" shall have the same meaning as that set forth in Subsection 1.2 except that the word "ROXANE" shall be substituted for the word "BIPI".

9.2 ROXANE shall keep BIPI fully advised on a current basis as to any new developments falling within the scope of Subsection 9.1 above. Such information shall be treated by BIPI in the same manner as ROXANE is to treat BIPI's Confidential Information pursuant to Section 4.3 hereof and the same exclusion shall apply.

9.3 BIPI shall have the right to supplement any patent filing ROXANE makes at BIPI's expense concerning any improvement invention made at ROXANE.

10. COMPLIANCE WITH LAWS

ROXANE will comply with the working requirements of the relevant laws and regulations of the various countries in the Territory, if any, in order that all of BIPI's Know-how be kept fully protected.

11. ROYALTIES

11.1 ROXANE hereby agrees to pay BIPI a running royalty of eleven percent (11%) of its Net Sales.

11.2 Royalty Payment Procedure - Accounting, crediting and remittal of the royalties shall be made every three (3) months within forty five (45) days after the end of each calendar quarter. Royalties accrued shall be payable to BIPI in U.S. Dollars to an account in any bank or other location which BIPI may from time to time designate to ROXANE in writing.

11.3 Royalty Reports - On or before the due date of each royalty payment pursuant to Subsection 12.2 hereof, ROXANE will deliver to BIPI a written statement showing in reasonable detail the sales of its Licensed Products during the preceding calendar quarter and accounting for royalties payable hereunder. ROXANE will keep separate records in sufficient detail to permit the determination of royalties payable hereunder and the preparation of the statements to be delivered to BIPI as required by this Subsection 11.3 and will, at the request of BIPI permit an accountant appointed by BIPI (except one to whom ROXANE has some reasonable objection), to have access to and examine during ordinary business hours such records as may be

necessary to verify the statements delivered to BIPI hereunder. Such accounting shall be at BIPI's expense.

12. INFRINGEMENT

12.1 Infringement by Unlicensed Parties

12.1.1 ROXANE undertakes to notify BIPI of any infringement in the Territory relating to the Know-how of which ROXANE becomes aware.

12.1.2 BIPI may, but shall not be obligated to, institute and conduct (with full power of settlement and compromises) such judicial or other proceeding as it may deem desirable against any such infringement or threatened infringement of which it is aware or which is brought to its attention. If BIPI does bring legal action within six (6) months after becoming aware of such infringement or threatened infringement (which action shall be at BIPI's sole cost and expense), then ROXANE shall continue to pay the royalties provided for herein during the pendency of such proceedings. BIPI shall be entitled to keep any recovery, whether by judgment or settlement, resulting from such action.

12.1.3 Should BIPI fail to institute such proceedings against any such infringement or threatened infringement within six (6) months after notice thereof is given by ROXANE, or within six (6) months after BIPI otherwise becomes aware thereof, whichever may first occur, then ROXANE may, but shall not be obligated to, bring legal action at its own cost and expense, and, if necessary in the name of BIPI, and shall discontinue payment of all royalties provided herein during the pendency of such proceedings. Any recovery obtained as a result of such action, whether by judgment or settlement shall belong solely to ROXANE.

12.1.4 In case both parties hereto should mutually agree to institute judicial or other proceedings against such infringement or threatened infringement cooperatively then ROXANE shall continue to pay during the pendency of such proceedings one-half (1/2) of the royalties provided for herein, and all costs and expenses of such action and all recoveries therefrom shall be divided equally between the parties hereto.

12.2 Infringement by ROXANE or Licensed Third Parties

12.2.1 If a notice of infringement is sent to, or a suit for infringement is brought against ROXANE or any of its Licensed Third Parties as a result of exercising its rights or performing its obligations and if BIPI is duly notified thereof and fails to take appropriate action at its own cost and expense in respect of said notice or suit on behalf of ROXANE or its Licensed Third Parties within a period of three (3) months after receipt of such notice by BIPI, then ROXANE shall have the option of:

12.2.1.1 Terminating the Agreement in respect of the Product in question by giving written notice of such termination to BIPI;

12.2.1.2 Taking a license from the party giving the notice or bringing the suit and deducting from any royalties payable to BIPI under this Agreement such royalties as are payable by ROXANE to such third party for such license; or

12.2.1.3 Defending the suit itself at its own cost and expense. If ROXANE elects to defend the suit, it shall so notify BIPI in writing and shall stop paying all royalties to BIPI hereunder during the pendency of such suit. If the defense of the suit is successful, ROXANE shall resume payment of royalties under this Agreement and pay to BIPI the accumulated unpaid royalties less the costs and expenses incurred by ROXANE in defense of the suit. If the defense is unsuccessful, the accumulated unpaid royalties need not be paid and ROXANE shall have the option of:

12.2.1.3.1 terminating this Agreement in respect of the Product in question as a whole; or in the country or territory involved in the suit;

12.2.1.3.2 taking a license from the party which brought the suit in which case the royalties payable to such third party shall be deducted from any royalties payable to BIPI hereunder.

13. RELATIONSHIP BETWEEN THE PARTIES

This Agreement is intended to and does create only the relationship of licensor and licensee and independent contractor between ROXANE and BIPI and does not establish between them any relationship as partners or coventurers, employer and employee or as principal and agent. In furtherance, but not in limitation of the foregoing sentence (a) ROXANE shall have no authority hereunder or otherwise to represent that it is the agent or employee of, or otherwise associated with BIPI, except as a licensee hereunder, to accept any order or enter into any contract or agreement or make any representations or warranties of any sort, or to assume or create any obligation, express or implied, on behalf of or binding or purportedly binding upon BIPI and (b) nothing herein shall authorize ROXANE to accept service of any writ, summons or other process or enter any appearance on behalf of BIPI in litigation or in any other manner to subject BIPI to the jurisdiction of any court, tribunal, or governmental agency.

14. EFFECTIVE DATE

This Agreement shall take effect as of January 1, 1995.

15. DURATION AND TERMINATION OF AGREEMENT

This Agreement shall continue in effect until January 1, 2005 and thereafter shall be automatically extended for additional successive five (5) year periods unless terminated as hereinafter provided. Either party may terminate this Agreement as at January 1, 2005 or as at the end of any of the aforesaid successive five (5) year periods thereafter, by notice in writing given to the other party at least three (3) months prior to the effective date of such termination.

16. EFFECTS OF AGREEMENT TERMINATION OR EXPIRATION

16.1 Termination or expiration of this Agreement shall not (a) relieve either party of its obligation to prevent disclosure of data or other information furnished to it of a confidential nature as provided in Paragraph 4, or (b) relieve either party of any obligation or liability accrued hereunder prior to such termination, including, without limitation, the obligations set forth in Paragraphs 9 and 11 hereof.

16.2 Upon termination or expiration, regardless of the occasion for such termination, ROXANE will forthwith make available to BIPI or its designee, and authorize its or their access to, all applications, data

and information relating to the Products theretofore filed by ROXANE with the government health authorities and similar governmental agencies under applicable statutes in the Territory, all to the end that such applications, data, and information may be used by BIPI or its designee in obtaining any necessary approvals or authorization for the sale or distribution of such Product. In addition, all specifications for such Product(s) shall then be returned to BIPI without any copies being retained.

16.3 Upon termination or expiration of this Agreement with respect to any trade dress, regardless of the occasion for such termination, ROXANE and its Licensed Third Parties will immediately cease the use of the trade dress.

16.4 Inventories of Products and the active ingredients, packaging materials and advertising materials therefor that remain at the time of the termination or expiration of this Agreement are to be offered to BIPI or to a third firm designated by BIPI for repurchase at cost price or manufacturing cost to ROXANE. Insofar as these inventories do not exceed a three (3) month supply, BIPI undertakes to repurchase these inventories or have them repurchased by a third party. All inventories in excess of a three (3) month supply may, if not repurchased as aforesaid, be sold or used by ROXANE or its Licensed Third Party(ies) in the normal course of their business. All unfilled orders pending at the effective date of termination or expiration automatically shall be deemed to have been canceled.

17. NON-ASSIGNABILITY

Neither party shall assign its rights or obligations to a third party not an affiliate of the assigning party without the written consent of the other party unless such assignment shall be made along with the assignment of the assigning party's entire pharmaceutical business and to an assignee which assumes in writing all of the assigning party's obligations under this Agreement.

18. NO IMPLIED WAIVER

Failure by ROXANE or BIPI on one or more occasions to avail itself of one or more clauses of this Agreement shall in no event be construed as a waiver thereof.

19. LEGAL REQUIREMENTS

All actions to be taken by the parties under this Agreement shall be taken in full compliance with all applicable laws and governmental regulations and the provisions of this Agreement shall be so construed as to effectuate such compliance. If any provision of this Agreement is determined to be illegal or unenforceable or incapable of construction consistent with legal or regulatory requirements, the enforceability of the other provisions of this Agreement shall not be affected and the parties will cooperate in agreeing upon some other method of performance which is consistent with such requirements and is as nearly as possible consistent with the purpose and intents of this Agreement.

20. NOTICE

Any notice required or permitted to be given to, or served upon, either party hereto pursuant to this Agreement shall be sufficiently given or served if sent to such party in writing by registered mail addressed to its at its address as set forth below, or to such other address as it shall designate by written notice given to the other party.

In case of a notice to ROXANE:

ROXANE LABORATORIES, INC.
Attn.: President
1809 Wilson Road
Columbus, OH 43228

In case of a notice to BIPI:

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.
Attn: President
900 Ridgebury Road, P. O. Box 368
Ridgefield, CT 06877

Copy to: Attn.: Secretary

21. COMPLETE UNDERSTANDING

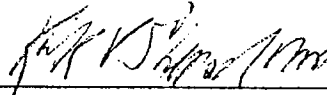
This Agreement embodies the entire understanding of the parties relating to the subject matter hereof. No amendment or modification of this Agreement or supplemental agreement hereto shall be valid or binding upon the parties unless made in writing and signed, in the case of ROXANE, by any person or persons thereunto duly authorized, and in the case of BIPI, by its President or one of its Vice-Presidents. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

22. JURISDICTION

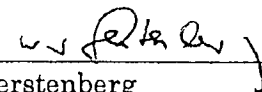
Any disputes that may arise from this Agreement which cannot be settled by the parties are to be decided by the courts having jurisdiction in the defendant's principal place of business in the basis of the laws existing therein.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate original by their duly authorized officers as of the day and year first above written.

ROXANE LABORATORIES., INC.

By: 
Kirk Shepard
Senior Vice President

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC. 

By: 
Werner Gerstenberg
President & Chief Operating Officer